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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. | |
|---------------------------------|---------------|----------------------|------------------------------|------------------|--|
| 10/030,801 | 06/14/2002 | Norbert Kothe | 100723- 12/Beil Wolff-291 | 4106 | |
| 759 | 90 09/26/2003 | | | | |
| Norris McLaughlin & Marcus | | | EXAMINER | | |
| 220 East 42nd S New York, NY | | | SAUNDERS | , DAVID A | |
| | | | ART UNIT | PAPER NUMBER | |
| | | | 1644 | | |
| | | | DATE MAILED: 09/26/2003 | | |

Please find below and/or attached an Office communication concerning this application or proceeding.

| | Application No. | Applicant(s) | KUTHE | etal | |
|--|--|--|---|-------------------------|--|
| Office Action Summary | Examiner 5 A UNL | DERS. | Group Art Unit | | |
| The MAILING DATE of this communication appears | on the cover sheet b | eneath the co | rrespondence add | ress | |
| Period for Reply | | | | | |
| A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO DF THIS COMMUNICATION. | EXPIRE | MONTH(S) | FROM THE MAILI | NG DATE | |
| Extensions of time may be available under the provisions of 37 CFR 1.13 from the mailing date of this communication. If the period for reply specified above is less than thirty (30) days, a reply If NO period for reply is specified above, such period shall, by default, ex Failure to reply within the set or extended period for reply will, by statute. | within the statutory minim pire SIX (6) MONTHS fror | um of thirty (30) on the mailing date | days will be considered of this communication | timely. | |
| Status | | | | | |
| ☐ Responsive to communication(s) filed on | | | | | |
| ☐ This action is FINAL . | | | | • | |
| ☐ Since this application is in condition for allowance except fo accordance with the practice under <i>Ex parte Quayle</i> , 1935 0 | | | the merits is close | d in | |
| Disp sition of Claims | / | | | | |
| (Sclaim(s) 1-29 | | is/are p | ending in the applic | ation. | |
| Of the above claim(s) | | | | | |
| ☐ Claim(s) | is/are a | _ is/are allowed. | | | |
| □ Claim(s) | | is/are re | ejected. | | |
| ☐ Claim(s). | | is/are o | bjected to. | | |
| (Claim(s) - 29 | | are sub | ject to restriction or | election | |
| Application Papers | | • | | | |
| ☐ See the attached Notice of Draftsperson's Patent Drawing F | | | | | |
| ☐ The proposed drawing correction, filed on | • • | ☐ disapproved | | | |
| ☐ The drawing(s) filed onis/are objected | to by the Examiner. | | • | | |
| ☐ The specification is objected to by the Examiner. | | | | | |
| ☐ The oath or declaration is objected to by the Examiner. | | | | | |
| Pri rity under 35 U.S.C. § 119 (a)-(d) | | | | | |
| ☐ Acknowledgment is made of a claim for foreign priority unde ☐ All ☐ Some* ☐ None of the CERTIFIED copies of the ☐ received. | | • | | | |
| ☐ received in Application No. (Series Code/Serial Number) | | | • | S ₁ . | |
| $\hfill\Box$ received in this national stage application from the International | ational Bureau (PCT R | ule 1 7.2(a)). | | | |
| *Certified copies not received: | | | • | | |
| Attachment(s) | | | | | |
| ☐ Information Disclosure Statement(s), PTO-1449, Paper No(s |) □ In | terview Summ | ary, PTO-413 | | |
| ☐ Notice of Reference(s) Cited, PTO-892 | | ☐ Notice of Informal Patent Application, PTO-152 | | | |
| ☐ Notice of Draftsperson's Patent Drawing Review, PTO-948 | | | | | |
| Office A | ction Summary | | | | |

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Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1-26, drawn to methods of fractionating plasma or serum.

Group II, claim(s) 27-28, drawn to products obtained by fractionating plasma or serum.

Group III, claim(s) 29, drawn to uses of products obtained by fractionating plasma or serum.

The inventions listed as Groups I, II and III do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: The IPEA has found that the method of claims 1-21 of Group I involves no inventive step. Since the IPEA has found prior art that anticipates or renders obvious the claims of Group(s) I, applicant has not provided a special technical feature which defines a contribution over the prior art, as required by PCT Rule 13.2, in order to provide for unity of invention. Furthermore claims 27-29 were not even presented during International examination. Note the statement of Lack of Unity by the IPEA indicated that claim 27 was drawn to a use of an Immunoglobulin preparation and not to an Immunoglobulin preparation per se. No claims corresponding to claims 28-29 were presented during the international phase.

In the event that applicant elects Group II, the following election of species is required:

This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The species are as follows:

An immunoglobulin preparation.

An antithrombin III preparation.

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Applicant is required, in reply to this action, to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

The claims are deemed to correspond to the species listed above in the following manner:

Claim 27 to an immunoglobulin preparation.

Claim 28 to an antithrombin III preparation.

The following claim(s) are generic: None.

The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons: Immunoglobulin and antithrombin III preparations are different compositions containing proteins with different structures and having different functions.

In the event that applicant elects Group III the following election of species is required:

This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

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The species are as follows:

Use of an immunoglobulin preparation.

Use of an antithrombin III preparation.

Use of a transferrin preparation.

Applicant is required, in reply to this action, to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

The claims are deemed to correspond to the species listed above in the following manner:

Claim 29 (first recited member) to Use of an Immunoglobulin preparation.

Claim 29 (second recited member) to Use of an antithrombin III preparation.

Claim 29 (third recited member) to Use of a transferrin preparation.

The following claim(s) are generic to a plurality of species: 29.

The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons: the uses of Immunoglobulin, antithrombin III and transferrin

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preparations would be conducted for the treating of different disease states; use of one such composition would not suggest use of any of the others.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David A Saunders, PhD whose telephone number is 703-308-3976. The examiner can normally be reached on Mon.-Thu., 8:00 am-5:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on 703-308-3973. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

DAS 9/25/03

David a Saunders
PRIMARY EXAMINER
ART UNIT 182-16 WY

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